AUG 2 3 2002

## 510(k) SUMMARY

(As required by 21 C.F.R. § 807.92)

K021819

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| *Submitted By:* | Lifescan, Inc.<br>1000 Gibraltar Drive<br>Milpitas, CA 95035 |
| *Contact Person:* | Mary Ellen Holden<br>Senior Regulatory Affairs Specialist<br>Lifescan, Inc.<br><br>Phone: (408) 942-3589<br>Fax: (408) 942-5906<br>E-mail: mholden@lfsus.jnj.com |
| *Date Summary Prepared:* | June 3, 2002 |
| *Device Name:* | One Touch® UltraSmart™ Blood Glucose Monitoring System |
| *Classification Names:* | (1) The One Touch® UltraSmart™ Meter and ONE TOUCH® Ultra™ Test Strip are Class II devices (21 CFR § 862.1345, Glucose Monitor).<br>(2) One Touch® Ultra™ Control Solution is a Class I device (21 CFR § 862.1660, Single Analyte Control).<br>(3) Sterile lancet, Lancing Device and accessories are Class I (exempt) devices (21 CFR § 878.4800, Lancet, Blood). |
| *Substantial Equivalence:* | The One Touch® UltraSmart™ Blood Glucose Monitoring System is substantially equivalent to the previously cleared One Touch® Ultra™ Blood Glucose Monitoring System (K002134), in that both devices are intended for the quantitative measurement of glucose in capillary whole blood (*for in vitro diagnostic use*) by people with diabetes and healthcare professionals. Both devices use the identical method of glucose detection and have the same safety and effectiveness. In addition, it is substantially equivalent to the One Touch® Profile® (K950727) Blood Glucose Monitoring System, a predicate device with similar advanced memory features. |
| *Description of the Device:* | The One Touch® UltraSmart™ System consists of the One Touch® UltraSmart™ Meter, One Touch® Ultra™ Test Strips, One Touch® Ultra™ Control Solution, UltraSoft™ Lancing Device, UltraClear™ cap and UltraSoft™ lancets. The One Touch® UltraSmart™ Meter, when used with the One Touch® Ultra™ Blood Glucose Test Strips, quantitatively measures glucose in capillary whole blood. The One Touch® Ultra™ Control Solution verifies the performance of the One Touch® Ultra™ Blood Glucose Test Strips. |

The UltraSoft™ Lancing Device, UltraClear™ cap and UltraSoft™ lancets are provided to facilitate obtaining a capillary blood sample.

*Statement of Intended Use:*

The One Touch® UltraSmart™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The One Touch® UltraSmart™ System is intended for use outside the body (*for in vitro diagnostic use*) by people with diabetes at home and by health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The One Touch® UltraSmart™ Blood Glucose Monitoring System provides the user with electronic logbook functions that store data such as insulin and oral medication doses, food intake, amount of exercise, and health information such as illnesses. The meter includes a data port that enables the user to download electronic logbook data to a personal computer

*Description of Similarities and Differences:*

The One Touch® UltraSmart™ System, provides the same glucose monitoring capability as the predicate device, the One Touch® Ultra™ System (K002134). One Touch® UltraSmart™ and One Touch® Ultra™ are essentially identical from the perspective of measuring glucose. In fact, they use the same One Touch Ultra™ test strip. The primary differences are in the advanced memory features. In this respect, the One Touch® UltraSmart™ System adds electronic logbook features similar to those offered commercially by the One Touch® Profile Meter (K950727).

The advanced memory features of One Touch® UltraSmart™ are similar to those of the One Touch® Profile Meter previously cleared for market (K950727). The One Touch® UltraSmart™ meter offers more memory, which allows advanced features not available with the predicate devices. The increased data storage expanded memory offers more opportunities to people with diabetes in managing their diabetes.

*Summary of Performance Data*

Laboratory studies and clinical studies demonstrate that the One Touch® UltraSmart™ Blood Glucose System provides equivalent performance to the One Touch® Ultra™ Blood Glucose System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Mary Ellen Holden
Sr. Regulatory Affairs Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

AUG 2 3 2002

Re: k021819
Trade/Device Name: ONE TOUCH® *UltraSmart*™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Holden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 3.0 ODE INDICATIONS FOR USE STATEMENT

### Indications for Use Statement

**510(k) Number:** K021819

**Device Name:** ONE TOUCH® *UltraSmart*™ Blood Glucose Monitoring System

**Indications for Use:**

The One Touch® *UltraSmart*™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The One Touch® *UltraSmart*™ System is intended for use outside the body (*for in vitro diagnostic use*) by people with diabetes at home and by health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The One Touch® *UltraSmart*™ Blood Glucose Monitoring System provides the user with electronic logbook functions that store data such as insulin and oral medication doses, food intake, amount of exercise, and health information such as illnesses. The meter includes a data port that enables the user to download electronic logbook data to a personal computer.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

Carol C Benson for Jean Cooper, DVM
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021819